It is critical because many times when a wireless caller calls 911, they either cannot talk or they do not know where they are.

The technology exists to help people in danger—I saw successful demonstration at the FCC just last week. And this legislation addresses the technical issues for industry, local government, and regional concerns, so no further delay is justified.

While lives are being saved in my area of Harris County where we are Phase Two complete for E–911, lives are still being needlessly lost in other areas where compliance is lagging.

Unfortunately, many other jurisdictions, including many in large rural areas of Texas do not have the resources necessary to upgrade their 911 systems.

We are not all safe when we travel on the roads until E–911 is up and running nationwide.

Public safety should be a top priority. States moving E–911 funds to other purposes deceives wireless consumers who saw that E–911 funding on their cell phone bills.

Coming from Texas, I know what it means to children and families hit by huge budget cuts, but E–911 is necessary—it is a proven life-saver. This legislation brings funding, accountability, and sensitivity to rural areas to the process and deserves strong support.

Mr. DINGELL. Mr. Speaker, consumers who dial 911 from their wireless phones expect emergency responders to be able to locate them, just as if they had dialed 911 from a wireless phone. All too often today, however, emergency responders have no such ability.

The House is poised to take an important step to address this problem. To this end, I am pleased to support H.R. 2898, the ''E-911 Implementation Act of 2003,'' as amended. This bill will take three important steps to help ensure that first responders can rapidly locate persons dialing 911 from a wireless phone. First, it will set up a federal office to help coordinate E-911 build-out. Second, it will provide federal matching grants to assist cash-strapped states and local communities in deploying E-911 technologies. Third, it will provide strong incentives to ensure that states no longer raid their E-911 funds for non-E-911 purposes.

I commend Chairmen TAUZIN and UPTON for working closely with Representatives ESHOO and SHIMKUS, the authors of the underlying bill and co-chairpersons of the Congressional E-911 Caucus. I am pleased to support this important bill and look forward to working with the appropriators to ensure that this grant program is fully funded.

Ms. SLAUGHTER. Mr. Speaker, I rise in strong support of H.R. 2898, the E–911 Implementation Act of 2003.

As a member of the Congressional E–911 Caucus, I want to thank my colleagues ANNA ESCHOO and JOHN SHIMKUS for their leadership and tireless advocacy on this critical public safety issue.

I would also like to recognize the efforts of a leader on this issue that many of you may not know—New York State Assemblyman David Koon.

Long before there was a Congressional E–911 Caucus, David was championing wireless enhanced 911. My constituents in Rochester have long appreciated David's tireless advocacy to get local government the resources they need to deploy E–911.

Today, 911 calls made on cell phones account for nearly a third of all emergency calls. By 2004, cell phones are expected to be the main source of 911 emergency calls. Most Americans with cells phones will tell you that they bought them for emergencies. They fully expect that if they have a health emergency or are in an accident—they can dial 9–1–1 and help will be on the way.

Back in 1999, Congress tried to make sure that happened by passing the Wireless Communications and Public Safety Act. However, today, most wireless phones still do not provide emergency dispatchers with automated caller location or identification information.

There's strong consumer demand for E–911, the technology needed to identify and locate wireless callers has long been available, and so Congress had to ask ''why the holdup?''

The chief barrier to universal E–911 deployment is money. Many localities will tell you they have had to put off implementing E–911 because it is too costly.

This was not supposed to happen.

Under the 1999 Act, States were given the power to collect surcharges on all cell phones, blackberries and other wireless devices to fund E–911 service. Unfortunately, the E–911 fund has become an easy target for looting by states that are struggling to cover shortfalls in law enforcement and emergency service budgets.

In New York State alone, over $200 million has been collected in surcharges since 1991.

This money is supposed to be earmarked for setting up a state-wide Wireless Enhanced 911 system, but instead the money has gone to the state police, who have spent the funds on departmental dry cleaning bills, ballpoint pens, travel, are leases, grounds maintenance for precincts and winter boots, according to the New York State comptroller's office.

I strongly believe that the millions of New York residents who pay the ''E–911 surcharge'' on their monthly cell phone bills are owed E–911 service when they need it. That's why I am an original cosponsor of H.R. 2898.

Under this measure, $500 million in grants would be available to the states over five years to establish and upgrade E–911 facilities. I also am encouraged that H.R. 2898 would penalize states that redirect E–911 funds collected from consumer's cell phone bills. That's the only way to make them honest.

Mr. Speaker, I strongly urge my colleagues to join me in passing this important legislation.

Its essential that we act on this legislation. It will save lives. Bright, beautiful, hopeful lives of Americans are at stake.

Ten years ago, Jennifer Koon, an 18-year old, was abducted from a mall parking lot in Rochester. She called 911. Her call could not be traced and Jennifer was killed.

In 1993, the technology was not readily available. Today that is not the case. Mr. Speaker passage of H.R. 2898 is essential to providing parents, like Assemblyman David Koon, with the assurance that their children will get the help they need when they dial 911—regardless of whether they dial it on a cell phone or on their home phone.

Mr. UPTON. Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore (Mr. HEFLEY). The question is on the motion offered by the gentleman from Michigan (Mr. UPTON) that the House suspend the rules and pass the bill, H.R. 2898, as amended.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

ANIMAL DRUG USER FEE ACT OF 2003

Mr. UPTON. Mr. Speaker, I move to suspend the rules and pass the Senate bill (S. 313) to amend the Federal Food, Drug, and Cosmetic Act to establish a program of fees relating to animal drugs, as amended.

The Clerk read as follows:

S. 313

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Animal Drug User Fee Act of 2003''.

SEC. 2. FINDINGS.

Congress finds as follows:

(1) Prompt approval of safe and effective new animal drugs is critical to the improvement of animal health and the public health.

(2) Animal health and the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for review of new animal drug applications.

(3) The fees authorized by this Act will be dedicated toward expediting the animal drug development process and the review of new and supplemental animal drug applications and investigational animal drug submissions as set forth in the goals identified, for purposes of part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate as set forth in the Congressional Record.

SEC. 3. FEES RELATING TO ANIMAL DRUGS.

Subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379f et seq.) is amended by adding at the end the following part:

''PART 4—FEES RELATING TO ANIMAL DRUGS

''SEC. 739. DEFINITIONS.

''For purposes of this subchapter:

''(1) The term 'animal drug application' means an application for approval of any new animal drug submitted under section 512(b)(1). Such term does not include either a new animal drug application submitted under section 512(b)(2) or a supplemental animal drug application.

''(2) The term 'supplemental animal drug application' means—

''(A) a request to the Secretary to approve a change in an animal drug application which has been approved; or

''(B) a request to the Secretary to approve a change to an application approved under section 512(c)(2) for which data with respect to safety or effectiveness are required.

''(3) The term 'animal drug product' means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is

uniquely identified by the labeler code and product code portions of the national drug code, and for which an animal drug application or a supplemental animal drug application has been approved.

''(4) The term 'animal drug establishment' means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within 5 miles of each other, at which one or more animal drug products are manufactured in final dosage form.

''(5) The term 'investigational animal drug submission' means—

''(A) the filing of a claim for an investigational exemption under section 512(j) for a new animal drug intended to be the subject of an animal drug application or a supplemental animal drug application, or

''(B) the submission of information for the purpose of enabling the Secretary to evaluate the safety or effectiveness of an animal drug application or supplemental animal drug application in the event of their filing.

''(6) The term 'animal drug sponsor' means either an applicant named in an animal drug application, except for an approved application for which all subject products have been removed from listing under section 510, or a person who has submitted an investigational animal drug submission that has not been terminated or otherwise rendered inactive by the Secretary.

''(7) The term 'final dosage form' means, with respect to an animal drug product, a finished dosage form which is approved for administration to an animal without substantial further manufacturing. Such term includes animal drug products intended for mixing in animal feeds.

''(8) The term 'process for the review of animal drug applications' means the following activities of the Secretary with respect to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions:

''(A) The activities necessary for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

''(B) The issuance of action letters which approve animal drug applications or supplemental animal drug applications or which set forth in detail the specific deficiencies in animal drug applications, supplemental animal drug applications, or investigational animal drug submissions and, where appropriate, the actions necessary to place such applications, supplements or submissions in condition for approval.

''(C) The inspection of animal drug establishments and other facilities undertaken as part of the Secretary's review of pending animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

''(D) Monitoring of research conducted in connection with the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

''(E) The development of regulations and policy related to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

''(F) Development of standards for products subject to review.

''(G) Meetings between the agency and the animal drug sponsor.

''(H) Review of advertising and labeling prior to approval of an animal drug application or supplemental animal drug application, but not such activities after an animal drug has been approved.

''(9) The term 'costs of resources allocated for the process for the review of animal drug applications' means the expenses incurred in connection with the process for the review of animal drug applications for—

''(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees consulted with respect to the review of specific animal drug applications, supplemental animal drug applications, or investigational animal drug submissions, and costs related to such officers, employees, committees, and contractors, including costs for travel, education, and recruitment and other personnel activities,

''(B) management of information, and the acquisition, maintenance, and repair of computer resources,

''(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies, and

''(D) collecting fees under section 740 and accounting for resources allocated for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

''(10) The term 'adjustment factor' applicable to a fiscal year refers to the formula set forth in section 735(8) with the base or comparator year being 2003.

''(11) The term 'affiliate' refers to the definition set forth in section 735(9).

''SEC. 740. AUTHORITY TO ASSESS AND USE ANIMAL DRUG FEES.

''(a) TYPES OF FEES.—Beginning in fiscal year 2004, the Secretary shall assess and collect fees in accordance with this section as follows:

''(1) ANIMAL DRUG APPLICATION AND SUPPLEMENT FEE.—

''(A) IN GENERAL.—Each person that submits, on or after September 1, 2003, an animal drug application or a supplemental animal drug application shall be subject to a fee as follows:

''(i) A fee established in subsection (b) for an animal drug application; and

''(ii) A fee established in subsection (b) for a supplemental animal drug application for which safety or effectiveness data are required, in an amount that is equal to 50 percent of the amount of the fee under clause (i).

''(B) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the animal drug application or supplemental animal drug application.

''(C) EXCEPTION FOR PREVIOUSLY FILED APPLICATION OR SUPPLEMENT.—If an animal drug application or a supplemental animal drug application was submitted by a person that paid the fee for such application or supplement, was accepted for filing, and was not approved or was withdrawn (without a waiver or refund), the submission of an animal drug application or a supplemental animal drug application for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

''(D) REFUND OF FEE IF APPLICATION REFUSED FOR FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any animal drug application or supplemental animal drug application which is refused for filing.

''(E) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an animal drug application or a supplemental animal drug application is withdrawn after the application or supplement was filed, the Secretary may refund the fee or portion of the fee paid under subparagraph (B) if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to refund the fee under this paragraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.

''(2) ANIMAL DRUG PRODUCT FEE.—Each person—

''(A) who is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product which has been submitted for listing under section 510, and

''(B) who, after September 1, 2003, had pending before the Secretary an animal drug application or supplemental animal drug application;

shall pay for each such animal drug product the annual fee established in subsection (b). Such fee shall be payable for the fiscal year in which the animal drug product is first submitted for listing under section 510, or is submitted for relisting under section 510 if the animal drug product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each animal drug product for a fiscal year in which the fee is payable.

''(3) ANIMAL DRUG ESTABLISHMENT FEE.—Each person—

''(A) who owns or operates, directly or through an affiliate, an animal drug establishment, and

''(B) who is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product which has been submitted for listing under section 510, and

''(C) who, after September 1, 2003, had pending before the Secretary an animal drug application or supplemental animal drug application,

shall be assessed an annual fee established in subsection (b) for each animal drug establishment listed in its approved animal drug application as an establishment that manufactures the animal drug product named in the application. The annual establishment fee shall be assessed in each fiscal year in which the animal drug product named in the application is assessed a fee under paragraph (2) unless the animal drug establishment listed in the application does not engage in the manufacture of the animal drug product during the fiscal year. The fee shall be paid on or before January 31 of each year. The establishment shall be assessed only one fee per fiscal year under this section, provided, however, that where a single establishment manufactures both animal drug products and prescription drug products, as defined in section 735(3), such establishment shall be assessed both the animal drug establishment fee and the prescription drug establishment fee, as set forth in section 736(a)(2), within a single fiscal year.

''(4) ANIMAL DRUG SPONSOR FEE.—Each person—

''(A) who meets the definition of an animal drug sponsor within a fiscal year; and

''(B) who, after September 1, 2003, had pending before the Secretary an animal drug application, a supplemental animal drug application, or an investigational animal drug submission,

shall be assessed an annual fee established under subsection (b). The fee shall be paid on or before January 31 of each year. Each animal drug sponsor shall pay only one such fee each fiscal year.

''(b) FEE AMOUNTS.—Except as provided in subsection (a)(1) and subsections (c), (d), (f), and (g), the fees required under subsection (a) shall be established to generate fee revenue amounts as follows:

''(1) TOTAL FEE REVENUES FOR APPLICATION AND SUPPLEMENT FEES.—The total fee revenues to be collected in animal drug application fees under subsection (a)(1)(A)(i) and supplemental animal drug application fees under subsection (a)(1)(A)(ii) shall be $1,250,000 in fiscal year 2004, $2,000,000 in fiscal year 2005, and $2,500,000 in fiscal years 2006, 2007, and 2008.

''(2) TOTAL FEE REVENUES FOR PRODUCT FEES.—The total fee revenues to be collected in product fees under subsection (a)(2) shall be $1,250,000 in fiscal year 2004, $2,000,000 in fiscal year 2005, and $2,500,000 in fiscal years 2006, 2007, and 2008.

''(3) TOTAL FEE REVENUES FOR ESTABLISHMENT FEES.—The total fee revenues to be collected in establishment fees under subsection (a)(3) shall be $1,250,000 in fiscal year 2004, $2,000,000 in fiscal year 2005, and $2,500,000 in fiscal years 2006, 2007, and 2008.

''(4) TOTAL FEE REVENUES FOR SPONSOR FEES.—The total fee revenues to be collected in sponsor fees under subsection (a)(4) shall be $1,250,000 in fiscal year 2004, $2,000,000 in fiscal year 2005, and $2,500,000 in fiscal years 2006, 2007, and 2008.

''(c) ADJUSTMENTS.—

''(1) INFLATION ADJUSTMENT.—The revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year to reflect the greater of—

''(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; United States city average) for the 12-month period ending June 30 preceding the fiscal year for which fees are being established; or

''(B) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia.

The adjustment made each fiscal year by this subsection will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2004 under this subsection.

''(2) WORKLOAD ADJUSTMENT.—After the fee revenues are adjusted for inflation in accordance with paragraph (1), the fee revenues shall be further adjusted each fiscal year after fiscal year 2004 to reflect changes in review workload. With respect to such adjustment:

''(A) This adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of animal drug applications, supplemental animal drug applications for which data with respect to safety or effectiveness are required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug protocol submissions submitted to the Secretary. The Secretary shall publish in the Federal Register the fees resulting from this adjustment and the supporting methodologies.

''(B) Under no circumstances shall this workload adjustment result in fee revenues for a fiscal year that are less than the fee revenues for that fiscal year established in subsection (b), as adjusted for inflation under paragraph (1).

''(3) FINAL YEAR ADJUSTMENT.—For fiscal year 2008, the Secretary may further increase the fees to provide for up to 3 months of operating reserves of carryover user fees for the process for the review of animal drug applications for the first 3 months of fiscal year 2009. If the Food and Drug Administration has carryover balances for the process for the review of animal drug applications in excess of 3 months of such operating reserves, then this adjustment will not be made. If this adjustment is necessary, then the rationale for the amount of the increase shall be contained in the annual notice setting fees for fiscal year 2008.

''(4) ANNUAL FEE SETTING.—The Secretary shall establish, 60 days before the start of each fiscal year beginning after September 30, 2003, for that fiscal year, animal drug application fees, supplemental animal drug application fees, animal drug sponsor fees, animal drug establishment fees, and animal drug product fees based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection.

''(5) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of animal drug applications.

''(d) FEE WAIVER OR REDUCTION.—

''(1) IN GENERAL.—The Secretary shall grant a waiver from or a reduction of 1 or more fees assessed under subsection (a) where the Secretary finds that—

''(A) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances,

''(B) the fees to be paid by such person will exceed the anticipated present and future costs incurred by the Secretary in conducting the process for the review of animal drug applications for such person,

''(C) the animal drug application or supplemental animal drug application is intended solely to provide for use of the animal drug in—

''(i) a Type B medicated feed (as defined in section 558.3(b)(3) of title 21, Code of Federal Regulations (or any successor regulation)) intended for use in the manufacture of Type C free-choice medicated feeds, or

''(ii) a Type C free-choice medicated feed (as defined in section 558.3(b)(4) of title 21, Code of Federal Regulations (or any successor regulation)),

''(D) the animal drug application or supplemental animal drug application is intended solely to provide for a minor use or minor species indication, or

''(E) the sponsor involved is a small business submitting its first animal drug application to the Secretary for review.

''(2) USE OF STANDARD COSTS.—In making the finding in paragraph (1)(B), the Secretary may use standard costs.

''(3) RULES FOR SMALL BUSINESSES.—

''(A) DEFINITION.—In paragraph (1)(E), the term 'small business' means an entity that has fewer than 500 employees, including employees of affiliates.

''(B) WAIVER OF APPLICATION FEE.—The Secretary shall waive under paragraph (1)(E) the application fee for the first animal drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay application fees for all subsequent animal drug applications and supplemental animal drug applications for which safety or effectiveness data are required in the same manner as an entity that does not qualify as a small business.

''(C) CERTIFICATION.—The Secretary shall require any person who applies for a waiver under paragraph (1)(E) to certify their qualification for the waiver. The Secretary shall periodically publish in the Federal Register a list of persons making such certifications.

''(e) EFFECT OF FAILURE TO PAY FEES.—An animal drug application or supplemental animal drug application submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid. An investigational animal drug submission under section 739(5)(B) that is submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person have been paid. The Secretary may discontinue review of any animal drug application, supplemental animal drug application or investigational animal drug submission from a person if such person has not submitted for payment all fees owed under this section by 30 days after the date upon which they are due.

''(f) ASSESSMENT OF FEES.—

''(1) LIMITATION.—Fees may not be assessed under subsection (a) for a fiscal year beginning after fiscal year 2003 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2003 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

''(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for animal drug applications, supplemental animal drug applications, investigational animal drug submissions, animal drug sponsors, animal drug establishments and animal drug products at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

''(g) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to be appropriated to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salary and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of animal drug applications.

''(2) COLLECTIONS AND APPROPRIATION ACTS.—

''(A) IN GENERAL.—The fees authorized by this section—

''(i) shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year, and

''(ii) shall only be collected and available to defray increases in the costs of the resources allocated for the process for the review of animal drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2003 multiplied by the adjustment factor.

''(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated

for the process for the review of animal drug applications—

''(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

''(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the amount in excess of 3 percent by which such costs fell below the level specified in subparagraph (A)(ii); and

''(II) such costs are not more than 5 percent below the level specified in subparagraph (A)(ii).

''(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section—

''(A) $5,000,000 for fiscal year 2004;

''(B) $8,000,000 for fiscal year 2005;

''(C) $10,000,000 for fiscal year 2006;

''(D) $10,000,000 for fiscal year 2007; and

''(E) $10,000,000 for fiscal year 2008;

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by animal drug application fees, supplemental animal drug application fees, animal drug sponsor fees, animal drug establishment fees, and animal drug product fees.

''(4) OFFSET.—Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriations Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.

''(h) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration for a waiver or reduction under subsection (d), or for a refund of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.

''(j) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in the process of the review of animal drug applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

''(k) ABBREVIATED NEW ANIMAL DRUG APPLICATIONS.—The Secretary shall—

''(1) to the extent practicable, segregate the review of abbreviated new animal drug applications from the process for the review of animal drug applications, and

''(2) adopt other administrative procedures to ensure that review times of abbreviated new animal drug applications do not increase from their current level due to activities under the user fee program.''.

SEC. 4. ACCOUNTABILITY AND REPORTS.

(a) PUBLIC ACCOUNTABILITY.—

(1) CONSULTATION.—In developing recommendations to Congress for the goals and plans for meeting the goals for the process for the review of animal drug applications for the fiscal years after fiscal year 2008, and for the reauthorization of sections 739 and 740 of the Federal Food, Drug, and Cosmetic Act (as added by section 3), the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall consult with the Committee on Energy and Commerce of the House of Representatives, the Committee on Health, Education, Labor, and Pensions of the Senate, appropriate scientific and academic experts, veterinary professionals, representatives of consumer advocacy groups, and the regulated industry.

(2) RECOMMENDATIONS.—The Secretary shall—

(A) publish in the Federal Register recommendations under paragraph (1), after negotiations with the regulated industry;

(B) present the recommendations to the Committees referred to in that paragraph;

(C) hold a meeting at which the public may comment on the recommendations; and

(D) provide for a period of 30 days for the public to provide written comments on the recommendations.

(b) PERFORMANCE REPORTS.—Beginning with fiscal year 2004, not later than 60 days after the end of each fiscal year during which fees are collected under part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 2(3) of this Act toward expediting the animal drug development process and the review of the new and supplemental animal drug applications and investigational animal drug submissions during such fiscal year, the future plans of the Food and Drug Administration for meeting the goals, the review times for abbreviated new animal drug applications, and the administrative procedures adopted by the Food and Drug Administration to ensure that review times for abbreviated new animal drug applications are not increased from their current level due to activities under the user fee program.

(c) FISCAL REPORT.—Beginning with fiscal year 2004, not later than 120 days after the end of each fiscal year during which fees are collected under the part described in subsection (b), the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

SEC. 5. SUNSET.

The amendments made by section 3 shall not be in effect after October 1, 2008, and section 4 shall not be in effect after 120 days after such date.

The SPEAKER pro tempore (Mr. BOOZMAN). Pursuant to the rule, the gentleman from Michigan (Mr. UPTON) and the gentlewoman from California (Ms. ESHOO) each will control 20 minutes.

The Chair recognizes the gentleman from Michigan (Mr. UPTON).

GENERAL LEAVE

Mr. UPTON. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days within which to revise and extend their remarks and to insert extraneous material on the Senate bill.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Michigan?

There was no objection.

Mr. UPTON. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, as the lead sponsor of the House-passed version of the Animal Drug User Fee Act of 2003, it is my pleasure today to manage S. 313, the Senate version of the same legislation on the floor.

What we are doing today is taking up the Senate-passed version of the Animal Drug User Fee Act and inserting the updated House language from H.R. 1260, which was approved by this body by voice last month. We are doing so because we determined that it was the best way to expedite the final passage of this much-needed legislation giving the FDA the authority to begin collecting the user fees this fiscal year needed to substantially beef up the new animal drug development and review process.

I would like to take the opportunity again to acknowledge and thank the gentlewoman from Colorado (Ms. DEGETTE), my original cosponsor; the gentleman from Louisiana (Mr. TAUZIN), our committee chairman; the gentleman from Michigan (Mr. DINGELL), ranking member; the gentleman from Florida (Mr. BILIRAKIS), Health Subcommittee chairman; and the gentleman from Ohio (Mr. BROWN), ranking member; and the Members on both sides of the aisle who have cosponsored the bill. I am grateful too for the hard work of our committee staff, Brent Delmonte, Pat Ronan, John Ford, and for the assistance that we have received from the FDA and the Animal Health Alliance. And also Jane Williams, my health care expert, deserves special merit as well.

Closely modeled after the very successful Prescription Drug User Fee Act of 1992 for human drugs, the Animal Drug User Fee Act is designed to give the Food and Drug Administration's Center for Veterinary Medicine the right resources and incentives needed to significantly improve the animal drug review process. The bill is supported by a broad coalition of veterinary and producer groups, including the American Veterinary Medical Association and the American Farm Bureau.

The legislation is sorely needed. Despite a statutory review time of 180 days, the average new animal drug application review currently takes about 1½ years and sometimes may drag on for even several years. This slowdown in review time is jeopardizing the supply of the new, safe, and effective animal drugs needed to keep our pets, flocks, and herds healthy and to provide American consumers with a safe and wholesome food supply.

Under this proposal, the additional revenues generated from fees paid by the pioneer animal drug industry would be dedicated for use in expediting the testing and review of new animal drugs in accordance with the performance goals that have been mutually agreed upon by the FDA and the animal drug industry.

As FDA Commissioner Mark McClellan has noted, a faster, more predictable review process is expected to spur more spending on research and development by the industry, promoting animal health by increasing the availability and diversity of new, safe, and effective products.

Mr. Speaker, I encourage my colleagues to vote for this much-needed bipartisan bill.

Mr. Speaker, I reserve the balance of my time.

Ms. ESHOO. Mr. Speaker, I yield myself such time as I may consume.

I am pleased that we are bringing the Animal Drug User Fee Act to the floor today. This is a bipartisan bill that enjoys strong support from a number of veterinary and farm organizations, as well as from a significant number of Members of Congress.

The Food and Drug Administration is a seriously underfunded agency. This has always been a source of concern to me given the critical mission that the FDA has of protecting our food supply, our drug supply, and protecting consumers. Over the last few years, Congress has taken a number of steps to rectify the funding shortfall. Last year we renewed the Prescription Drug User Fee Act for the second time. We also passed new legislation, the Medical Device User Fee and Modernization Act, which created a user fee program for medical devices that will help speed new technology to the patients who need them.

The Animal Drug User Fee Act is the next in this slate of bills that are aimed at boosting FDA's resources. This bill will provide the FDA's Center for Veterinary Medicine with an additional $48 million over the next 5 years. The money will be directed and solely directed to hiring new staff and acquiring the additional resources needed to approve the applications for animal drugs in a speedier manner while still maintaining FDA's gold standard of safety and efficacy.

This bill will touch everyone's life in multiple ways, even though they may not think so, whether it is through lifesaving medications for pets or better, less toxic medications for farm animals. It is in everyone's best interest to have an FDA that is equipped to review these new drug applications in a safe and in a timely manner.

I want to thank the gentlewoman from Colorado (Ms. DEGETTE), who cannot be here. She is the one who really should be standing here rather than myself, and the gentleman from New York (Mr. TOWNS) for all of their hard work they put in on this bill with the gentleman from Michigan (Mr. UPTON), its sponsor. It is to their credit that it will be law. I also want to thank the gentleman from Michigan (Mr. DINGELL), our distinguished ranking member, and certainly his staff, John Ford, whom over and over and over again does superb work and tireless work in this specific case to help bring this bill through the committee and to the floor of the House. So to the gentleman from Michigan (Mr. UPTON), our chairman, I salute him. This is a great day for him on the floor because both the E–911 Implementation Act of 2003 and certainly this bill, the Animal Drug User Fee Act of 2003, are very important ones that push the edges of the envelope out and really help to protect consumers and the people of our country. So I salute him.

Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

Mr. UPTON. Mr. Speaker, I yield myself such time as I may consume.

I want to thank the gentlewoman from California (Ms. ESHOO), a very able replacement for the gentlewoman from Colorado (Ms. DEGETTE), who I too regret she is not here. This has been a bipartisan effort from get-go.

Mr. TAUZIN. Mr. Speaker, I am proud to rise in favor of S. 313, the Animal Drug User Fee Act (''ADUFA''), sponsored in the House by my good friend from Michigan, Mr. UPTON.

This legislation, modeled after the successful Prescription Drug User Fee Act (PDUFA), is designed to decrease the review time of new animal drugs at the Center for Veterinary Medicine (CVM) of the Food and Drug Administration (FDA). This legislation is essential to the health of pets and livestock, as well as food safety. CVM is currently experiencing sizable delays in its review of drug applications. These delays are problematic for CVM, drug sponsors, pet owners, veterinarians, and livestock producers.

Simply put, the CVM needs an infusion of funds to address review shortcomings. The slowdown of the approval process threatens to reduce the tools available to livestock and poultry producers to produce vibrant stock and to combat animal disease. The slowdown of the approval process also threatens the health and well being of family pets and zoo animals. Further, delays at CVM have a chilling effect on the animal health industry's investment in important research and development, threatening the pipeline of new products.

In conclusion, this is a very modest program, but one that is desperately needed. The pace of animal drug reviews has slowed in recent years and the FDA needs the proper resources to hire more reviewers. Please join me in supporting S. 313, The Animal Drug User Fee Act of 2003.

Mr. GREEN of Texas. Mr. Speaker, I rise today in support of S. 313, the Animal Drug User Fee Act. This legislation is modeled after the successful Prescription Drug User Fee Act, which ensures that consumers have timely access to lifesaving drugs. ADUFA would establish the same expedited process to ensure that pets and livestock also have access to groundbreaking pharmaceuticals.

Despite a current requirement that limits the review time of a new animal drug application to 180 days, the review process takes an average of 1.5 years to complete, with some applications taking several years. Eighty-eight percent of original new animal drug applications are overdue, the longest day being 717 days.

Mr. Speaker, we wouldn't stand for that kind of delay for people, and I don't think that Man's Best Friend, or the livestock that feeds all Americans, should have to either. I support this legislation, and am happy to see it on our agenda.

However, I would point out that this House has not yet acted on legislation which would authorize the FDA to require pharmaceuticals manufacturers to test their products on children. For too long, doctors have been guessing about how best to treat our children. Kids are being used as guinea pigs because pharmaceutical companies haven't done the testing necessary to ensure that their products are safe and effective for kids. Many of us have been fighting for several years to ''codify the rule,'' and I am anxious to work on legislation that would do that. As important as animals are, nothing is more important than the health and safety of our children.

It is high time for us to put the interests of our children first. I urge the leadership of the House of Representatives to take up legislation which would ensure that the FDA has the authority it needs to require prescription drug manufacturers to test their products for children.

Mr. UPTON. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Michigan (Mr. UPTON) that the House suspend the rules and pass the Senate bill, S. 313, as amended.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the Senate bill, as amended, was passed.

A motion to reconsider was laid on the table.

RECOGNIZING OUTSTANDING CONTRIBUTIONS OF CHRISTIAN COLLEGES AND UNIVERSITIES

Mr. HOEKSTRA. Mr. Speaker, I move to suspend the rules and agree to the resolution (H. Res. 300) recognizing the outstanding contributions of the faculty, staff, students, and alumni of Christian colleges and universities, as amended.

The Clerk read as follows:

H. RES. 300

Whereas the United States has benefited greatly from over 1,000 Christian colleges, beginning with the Nation's first Christian college in 1636;

Whereas 900 such campuses continue to identify themselves as religious institutions, adding to the rich diversity of higher education in the Nation;

Whereas more than 125 Christian colleges, as members or affiliates of the Council for Christian Colleges & Universities provide faith-infused scholarship and service that produces students strongly dedicated to their faith, values, and morals;

Whereas the Council's member institutions are located in 30 States, represent more than 30 religious traditions, and with 15,000 faculty members serve more than 200,000 students;

Whereas nearly all (99 percent) of students at Council institutions participate in some form of service and learning through extracurricular activities and 80 percent participate in experiential learning;

Whereas alumni from Council institutions reported that their college education helped them develop moral principles and a sense of